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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,846	09/17/2001	Y. Tom Tang	PF-0556-1 DIV	9384

27904 7590 05/15/2003

INCYTE CORPORATION (formerly known as Incyte
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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,846

Applicant(s)

TANG ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-17, 19, 20, 24-28, and 46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- ☐ Interview Summary (PTO-413) Paper No(s) ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, 16, and 17, drawn to polypeptides, classified in class 530, subclass 350.
 - II. Claims 3-7, 9, 11, 12, and 46, drawn to polynucleotides, a vector, a host cell, and methods of expression, classified in class 536, subclass 23.5 and class 435, subclass 320.1, 325, and 69.1.
 - III. Claim 8, drawn to a transgenic organism, classified in class 800, subclass 13.
 - IV. Claims 13-15, drawn to a method of detecting polynucleotides, classified in class 435, subclass 6.
 - V. Claims 19 and 26, drawn to a method of screening a compound for effectiveness as an agonist of a polypeptide or a method of screening for a compound that modulates the activity of a polypeptide, classified in class 435, subclass 7.1.
 - VI. Claim ²⁰~~16~~, drawn to a composition comprising an agonist identified by a method of claim 19, classification depends upon the structure of the agonist.
 - VII. Claim 24, drawn to a method for treating a disease or condition associated with overexpression of functional TRXP, classified in class 514, subclass 2.
 - VIII. Claim 25, drawn to a method of screening for a compound that specifically binds to a polypeptide, classified in class 435, subclass 7.1.

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- IX. Claim 27, drawn to a method of screening a compound for effectiveness in altering expression of a target polynucleotide, classified in class 435, subclass 6.
- X. Claim 28, drawn to a method of assessing toxicity of a test compound, classification depends upon the structure of the test compound.
2. The inventions are distinct, each from the other for the following reasons. Inventions I, II, III, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different products, polypeptides, polynucleotides, transgenic organism, or a composition comprising an agonist of a polypeptide. These products have completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations.
3. Inventions IV, V, and VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instant case, the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. Invention IV requires detecting polynucleotides; Invention V requires screening a compound for effectiveness as an agonist or a compound that modulates the activity of a polypeptide; Invention VII requires treating a disease or condition associated with overexpression of functional TRXP; Invention VIII requires screening for a

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compound that either specifically binds to a polypeptide; Invention IX requires screening a compound for effectiveness in altering expression of a target polynucleotides; whereas Invention X requires assessing toxicity of a test compound. Each method is unique and not required another. Thus, all the methods are exclusive.

4. Invention I is related to Inventions V, VII, and VIII as product and process of use.

The invention can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instant case, the polypeptide may be used in a materially different process such as to immunize mice to produce antibodies.

5. Invention II is related to Inventions IV, V, and VII-X as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instant case, the polynucleotides may be used in a materially different process, such as production of polypeptides.

6. Invention III is related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process

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of using that product (MPEP §806.05 (h)). In the instant case, the transgenic organism may be used in a materially different process, such as to study the biological functions of a polypeptide or a polynucleotide.

7. Invention I is an independent invention from Inventions IV, IX, and X; Invention III is an independent invention from Inventions V and VII-X; Invention III is an independent invention from Inventions V and VII-X; Invention VI is an independent invention from Inventions IV and VII-X. The different inventions are drawn to distinct product and method inventions.
8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
10. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
May 6, 2003


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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